

**CHEMICALS UNDER CONSIDERATION FOR POSSIBLE LISTING
VIA THE AUTHORITATIVE BODIES MECHANISM**

**PACKAGE 6c
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Reproductive and Cancer Hazard Assessment Section
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

The chemical listed in the Table below meets the criteria for listing under Proposition 65 via the authoritative bodies listing mechanism. The regulatory guidance for listing by this mechanism is set forth in Title 22, California Code of Regulations (22 CCR), Section 12306. For example, the regulations include provisions covering the criteria for evaluating the documentation and scientific findings by the authoritative body to determine whether listing under Proposition 65 is required.

For carcinogenicity, the authoritative bodies are U.S. Environmental Protection Agency (U.S. EPA), International Agency for Research on Cancer (IARC), Food and Drug Administration (FDA), National Institute for Occupational Safety and Health (NIOSH) and the National Toxicology Program (NTP). OEHHA has found that the chemical in the table below has been "formally identified" as causing cancer according to the regulations covering this issue (22 CCR 12306(d)). The chemical below is the subject of a report published by the authoritative body which concludes that the chemical causes cancer or reproductive toxicity or has been included on a list of chemicals causing these effects issued by the authoritative body. Also, the document specifically and accurately identifies the chemical and the document meets one or more of the criteria outlined in 22 CCR 12306(d)(2).

OEHHA also finds that the criteria given in regulation for "as causing cancer" (22 CCR 12306(e)) have been satisfied for the chemical in the table below. In making this evaluation, OEHHA relied upon the discussion of data by the authoritative body in making its findings that the specified chemical causes such effects. A brief discussion of the relevant carcinogenesis studies providing evidence for the findings is presented below. The statements in bold reflect data and conclusions that satisfy the criteria for the sufficiency of evidence for carcinogenicity (22 CCR 12306(e)).

Chemical	CAS No.	Chemical Use	Reference
<i>o</i> -Phenylphenol	90-43-7	Germicide and fungicide used on citrus fruits and vegetables	U.S. EPA (1994)

o-Phenylphenol (CAS No. 90-43-7)

Increased incidence of malignant and combined malignant and benign uncommon tumors to an unusual degree in male rats.

The U.S. EPA (1994) has classified *o*-phenylphenol and sodium *o*-phenylphenate as Group B2 carcinogens based on sufficient evidence in animals. In 1987, sodium *o*-phenylphenate was identified by the International Agency for Research on Cancer (IARC) as a Group 2B carcinogen and was listed under Proposition 65 on January 1, 1990. IARC (1983; 1999) has concluded that there is limited evidence for the carcinogenicity of *o*-phenylphenol in experimental animals. The relevant studies cited by U.S. EPA (1994) are described below.

Male F344/DuCrj rats were treated with a pelleted diet of *o*-phenylphenol (0, 0.625, 1.25 and 2.5% of the diet) for 91 weeks. Statistically significant increases in the combined incidence of urinary bladder papilloma and carcinoma were observed (0/24, 0/20, 23/24, and 4/23 for control, low-, mid- and high-dose groups, respectively). Among the tumor bearing animals, urinary bladder transitional cell carcinomas were found in 20/23 of the 1.25% dose group and 2/4 of the 2.5% group.

In 13-week studies with male and female F344/DuCrj rats, animals were treated with *o*-phenylphenol (0.156, 0.313, 0.625, 1.25, or 2.5% of the diet). In the 1.25% dose group, transitional cell papillomas of the urinary bladder were observed in 6/12 male rats. No tumors were found in controls or in any other dose group. No tumors were observed in female rats.

U.S. EPA cited another study in which four groups of male F344/DuCrj rats were treated with either *o*-phenylphenol (1.25% in the diet); *o*-phenylphenol (1.25% in the diet) plus 0.4% sodium bicarbonate in drinking water; sodium *o*-phenylphenate (1.25% in the diet); or sodium *o*-phenylphenate (1.25% in the diet) plus 1% ammonium chloride in drinking water for 26 weeks. Urinary bladder papillomas were observed in 12/31 rats treated with *o*-phenylphenol and in 20/31 rats treated with *o*-phenylphenol plus sodium bicarbonate. In sodium *o*-phenylphenate-treated rats, the incidence of urinary bladder papilloma was 21/31, with one carcinoma also observed. In rats treated with sodium *o*-phenylphenate plus ammonium chloride, the incidence of urinary bladder papilloma was 3/31. The study authors noted that these results indicated that tumor incidence was increased by alkalinity and that the earlier finding that sodium *o*-phenylphenate was “more carcinogenic” than *o*-phenylphenol resulted from the higher alkalinity of sodium *o*-phenylphenate.

REFERENCES

International Agency for Research on Cancer (IARC, 1983). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Volume 30:329-344. *Miscellaneous Pesticides*. IARC, Lyon, France.

International Agency for Research on Cancer (IARC, 1999). *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Volume 73 as reported on the IARC website at <http://193.51.164.11/past&future/OCT98.html>. *Some Chemicals that Cause Tumours of the Kidney or Urinary Bladder in Rodents, and Some Other Substances*. IARC, Lyon, France.

U.S. Environmental Protection Agency (U.S. EPA, 1994). *Memorandum: Carcinogenicity Peer Review of Orthophenylphenol (OPP) and Sodium Orthophenylphenol (SOPP)*. Office of Prevention, Pesticides and Toxic Substances. August 24, 1994.